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APPLICATION NO.	F	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,173 🗸		11/06/2003	Xi Chen	11134-013-999	4030
20583	7590	08/10/2006		EXAM	INER
JONES DA	Y			AULAKH, C	HARANJIT
222 EAST 4		0017		ART UNIT	PAPER NUMBER

DATE MAILED: 08/10/2006

Amendment due 11/10/06

Please find below and/or attached an Office communication concerning this application or proceeding.



	Application No.	Applicant(s)
,		
055 - 4 - 4 0	10/705,173	CHEN ET AL.
Office Action Summary	Examiner	Art Unit
	Charanjit S. Aulakh	1625
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the	e correspondence address
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be will apply and will expire SIX (6) MONTHS find, cause the application to become ABANDO.	ON. timely filed om the mailing date of this communication. NED. (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed on 17 Ju	uly 2006.	
·—	action is non-final.	
3) Since this application is in condition for allowar		
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11,	453 O.G. 213.
Disposition of Claims		
4) ⊠ Claim(s) 1-52 is/are pending in the application. 4a) Of the above claim(s) 3 is/are withdrawn fro 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) 1,2 and 4-52 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or	om consideration.	
Application Papers		
9) The specification is objected to by the Examine		
10) The drawing(s) filed on is/are: a) acce	•	
Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct	•	
11) The oath or declaration is objected to by the Ex	•	
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of	s have been received. s have been received in Applica ity documents have been recei ı (PCT Rule 17.2(a)).	ation No ved in this National Stage
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) X Interview Summar	
 Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/15.6/14, 6/8. 	Paper No(s)/Mail I 5) Notice of Informal 6) Other:	Date. <u>8/4/06</u> . Patent Application (PTO-152)

U.S. Patent and Trademerk Office PTOL-326 (Rev. 7-05) Art Unit: 1625

DETAILED ACTION

1. According to paper filed on July 17, 2006, the applicants elected group I with traverse for further prosecution in response to restriction requirement. However, during a telephone conversation with the applicant's attorney on Aug. 4, 2006, it was found that there was a confusion regarding the value of variable Q. The examiner wrote the original restriction requirement based on the assumption that when Q represented – N(R)-(C1-C3)alkylene, -N(R)- group was substituted with C1-C3 alkylene group and therefore, Q-containg ring was always a 5-membered ring containing 1N atom.

However, during a telephonic conversation with the applicant's attorney on Aug. 4, 2006, the attorney mentioned that when Q represented N(R)-(C1-C3)alkylene, alkylene group represents part of the ring and therefore, Q-containing ring can be a 6, 7 or 8-membered ring containing 1 N atom. Due to this confusion, an agreement was reached to rewrite the restriction requirement as following:

Election/Restrictions

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-5 and 35-52, drawn to compounds of formula (I) where Q represents
 –N(R)-, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 548, subclass 421.
 - II. Claims 1, 2 and 4-52, drawn to compounds of formula (I) where Q represents

 -N(R)-(C1) alkylene, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 546, subclass 70.

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III. Claims 1, 2, 4, 5 and 35-52, drawn to compounds of formula (I) where Q represents –N(R)-(C2-C3) alkylene, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 540, subclass 476.

- 3. The inventions I, II and III as defined above are patentably distinct, each from the other since they are structurally so divergent that a reference showing compounds of invention I would not render compounds of inventions II or III prima facia obvious.

 Search required for e.g; compounds of invention I in class 548 is not the same search required for e.g; compounds of invention II in class 546 and therefore, constitutes a burdensome search.
- 4. During a telephone conversation with the applicant's attorney, Mr. Roger Rich on Aug. 4, 2006, a provisional election was made with traverse to prosecute the invention of group II, claims 1, 2 and 4-52. Affirmation of this election must be made by applicant in replying to this Office action. Claim 3 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
- 5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 6-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply

with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed: Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on atleast four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, the state of the prior art, unpredictability and the breadth of claims. In regard to making hydrates, solvates and prodrugs of instant compounds of formula II (claims 6-52), there is no teaching or guidance present in the specification for preparing specific hydrates, solvates and prodrugs. There is not even a single example present in the specification for preparing hydrates, solvates and prodrugs of instant compounds of formula II. There is lot of unpredictability regarding stability of hydrates

and solvates of compounds in the art. Similarly, there is lot of unpredictability regarding

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effectiveness of various forms of prodrugs following their in vivo administration. The instant compounds of formula II encompasses hundreds of thousands of compounds based on the values of variables R1, R2, R", L1, L2, X, Y, Z and n and therefore, in absence of such teachings, guidance, presence of working examples and unpredictability, it would require undue experimentation to select specific hydrates, solvates and prodrugs which will be stable and also effective following their in vivo administration.

In regard to using instant compounds of formula II (see claims 35-52) for treating various disease conditions, the specification mentions in example 80 on pages 92 and 93 that modulatory activity of instant compounds can be assessed using the in vitro and in vivo assay methods described above and furthermore, mentions that exemplary compounds demonstrated MCHR1 modulatory activity. However, there is no teaching in the specification whether the compounds are agonists or antagonists at MCHR1 receptors. The utility of instant compounds will be different based on agonist versus antagonist activity of instant compounds at MCHR1 receptors. There is no teaching or direction present regarding specific in vitro or in vivo assays for evaluating agonist versus antagonist activity of instant compounds at MCHR1 receptors. There are no working examples present showing efficacy of instant compounds in known in vivo or in vitro models of any disease condition including obesity, eating disorders, anxiety disorders and mood disorders. There is no teaching either in the specification or in the prior art regarding well known utility of structurally closely related compounds for treating any disease condition including obesity, eating disorders, anxiety disorders and

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mood disorders. The instant compounds of formula II encompasses hundreds of thousands of compounds based on the values of variables R1, R2, R", L1, L2, X, Y, Z and n and therefore, in absence of such teachings, guidance, presence of working examples and the state of the prior art, it would require undue experimentation to evaluate agonist versus antagonist activity at MCHR1 receptors and to demonstrate the efficacy of instant compounds in known in vitro or in vivo models of various disease conditions including obesity, eating disorders, anxiety disorders and mood disorders and hence their utility for treating these disease conditions.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9, Claims 1, 2 and 4-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claim 1, variable R1 is defined but is not present in formula (I). It appears that (Ar) group should be substituted with (R1) n and not (R)n. An appropriate correction is required.

In independent claim 1 (lines 42-46) and claim 6 (lines 91-95), variables R5-R18 are mentioned to contain R groups. However, according to the definition of these variables, these variables do not contain R group at all. The only variable which contains R group is variable Q in formula (I) in claim 1. An appropriate correction is required.

In independent claim 6, the terms --- hydrates, solvates and prodrugs --- are indefinite since specific hydrates, solvates and prodrugs are not defined.

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In claims 41 and 50, the term -modulating --- is indefinite since it is not clear whether the MCHR is activated, inhibited or unchanged?

In claim 45, specific disorders or conditions mediated by MCHR are not defined.

Claim 15 recites the limitation "p is 1, 2 or 3" in claim 13. There is insufficient antecedent basis for this limitation in the claim.

10. Claims 1, 2, 4, 5 and 35-52 are objected for containing non-elected subject matter.

Allowable Subject Matter

11. The following is a statement of reasons for the indication of allowable subject matter:

The instant compounds directed to the elected subject matter are allowable over the prior art since they are neither disclosed nor obvious over the prior art. In the prior art, Chen (U.S. Patent 6,858,619) discloses fused heterocyclic compounds which are closely related to the instant compounds. However, the closely related compound (see example 10 in column 31) differs form the instant compounds in lacking instant variable Z and furthermore, there is no teaching or motivation in the prior art to modify the compounds of Chen to prepare the instant compounds.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor; Thomas McKenzie can be reached on (571)272-0670. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

> C-S Aucarh Charanjit S. Aulakh **Primary Examiner** Art Unit 1625

	Application No.	Applicant(s)					
Interview Summary	10/705,173	CHEN ET AL.					
interview Summary	Examiner	Art Unit					
	Charanjit S. Aulakh	1625					
All participants (applicant, applicant's representative, PTO personnel):							
(1) Charanjit S. Aulakh.	(3)						
(2) Roger Rich.	(4)						
Date of Interview: <u>04 August 2006</u> .							
Type: a)⊠ Telephonic b)☐ Video Conference c)☐ Personal [copy given to: 1)☐ applicant 2	2) applicant's representative	e]					
Exhibit shown or demonstration conducted: d) Yes If Yes, brief description:	e) <u></u> No.						
Claim(s) discussed:							
Identification of prior art discussed:							
Agreement with respect to the claims f) was reached. g)☐ was not reached. h)☐ N	N/A.					
Substance of Interview including description of the general reached, or any other comments: <u>A telephone call was maderesponse to restriction requirement. Following conversation to rewrite restriction requirement based on the value of varing group II (Q is -N(R)-(C1)-alkylene with traverse. (A fuller description, if necessary, and a copy of the amend</u>	de to the applicant's attorney in with the applicant's attorney, in with the applicant's attorney, in with the applicant's attorney, in with the applicant's attorney.	to clarify the elected group in an agreement was reached ion, the applicants elected					
allowable, if available, must be attached. Also, where no callowable is available, a summary thereof must be attached	opy of the amendments that v	vould render the claims					
THE FORMAL WRITTEN REPLY TO THE LAST OFFICE A INTERVIEW: (See MPEP Section 713.04). If a reply to the GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW DATE, OR THE SUBSTANCE OF THE INTERVIEW OF THE INTERVIEW OF THE SUBSTANCE OF THE INTERVIEW OF T	last Office action has already OF ONE MONTH OR THIRTY ERVIEW SUMMARY FORM,	been filed, APPLICANT IS Y DAYS FROM THIS WHICHEVER IS LATER, TO					
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Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.	Examiner's sign	ature, if required					

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ATTY DOCKET NO. APPLICATION NO
11134-013-999 10/705,173

APPLICANT
Chen et al.

FILING DATE
November 6, 2003 1614

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIAT
CA	B01	5,441,956	8/15/95	Vecchietti et al.	3		. 1
CA	B02	5,457,208	10/10/95	Portoghese et al.			
1'A	B03	20030023085	1/30/03	Chen et al.	'		
CA	B04	20030176694	9/18/03	Chen et al.			•
CA	B05	20030199549	10/23/03	Burnett et al.			

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CA	B06	WO91/07966	6/13/91	PCT							
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(A	B08	WO95/13071	5/18/95	PCT							
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		CHIER REFERENCES Legisdien Suthor, Title, Date, Pertinent Pages, Etc.)
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CA	A02	5,436,128	7/25/95	Harpold et al.	,						
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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U.S. Patent and Trademark Office PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 20060807

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner indicates he or she will do so. It is the examiner indicates he or she will do so. which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the

interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the out typographical errors or unreatiable script in Onice actions or the like, are excluded from the interview recordation procedures believes that the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following Information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable Items required below concerning the substance of the interview.

- A complete and proper recordation of the substance of any interview should include at least the following applicable items:
- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed, 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
 - (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.